

P A T E N T

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Erik E. EMSTAD et al.	Confirmation No.:	3659
Serial No.:	10/726,329	Examiner:	James L. Swiger III
Filed:	December 1, 2003	Group Art Unit:	3733
Docket No.:	1292.1228101	Customer No.:	28075
Title:	SPINAL ACCESS INSTRUMENT		

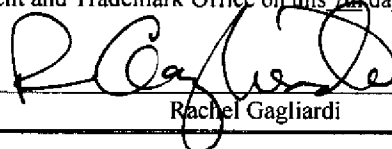
PRE-APPEAL BRIEF REQUEST FOR REVIEW

MAIL STOP: AF
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P.O. Box 1450
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CERTIFICATE FOR ELECTRONIC TRANSMISSION:

The undersigned hereby certifies that this paper or papers, as described herein, are being electronically transmitted to the U.S. Patent and Trademark Office on this 7th day of November, 2008.

By



Rachel Gagliardi

Dear Sir:

This Amendment is being filed in response to the Advisory Action mailed October 22, 2008 and the Office Action mailed July 8, 2008, with a shortened statutory period set to expire on October 8, 2008. Applicants hereby request a one-month extension of time. Please charge the appropriate fee and any additional fees or credit overpayment to Deposit Account No. 50-0413.

Applicants submit that the Examiner's rejections contain at least the following clear errors and/or omissions of one or more essential elements needed for a prima facie rejection.

Claims 1-13 and 16-21 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Jacobson (U.S. Patent No. 4,545,374) in view of Ogawa et al. (U.S. Patent No. 5,976,146). Applicants submit that this rejection is made in error. Jacobson does not appear to teach all of the elements of claim 1. The Examiner asserts that Jacobson teaches a blade member 18 that is capable of moving relative to a placement wire 33. The Examiner appears to have misinterpreted the claims. Independent claim 1 recites, in part, "a placement wire having a first end positionable at one of the first and second pedicle locations, the blade member being slidably positionable over the placement wire with the placement wire received within at least a portion of the blade member." Applicants submit that Jacobson's teaching of

a rongeur forceps 18, 60 to be inserted through a cannula 30 having anchor wires 33 does not disclose or suggest the elements as claimed. Jacobson specifically teaches, “the anchor wires 33 are slidably inserted into one or more bores 34 defined by the member 31.” (Col. 9, lines 45-47 and FIG. 13. Jacobson thus appears, at best, to teach the cannula member 31 as being slidably positionable over the wires 33. The rongeur forceps 18, 60 are taught as being inserted through the cannula, but are not taught or suggested as being placed over any wire. Jacobson thus does not appear to teach or suggest the elements of the claim.

In addition to Jacobson not teaching all of the elements of claim 1, Ogawa et al. do not appear to cure the failings of Jacobson. Neither Jacobson nor Ogawa et al. appear to teach the limitation of “the blade member being slidably positionable over the placement wire with the placement wire received within at least a portion of the blade member.” On pages 2 and 3 of the Office Action, the Examiner appears to state that Ogawa teaches this limitation:

“Ogawa et al. discloses . . . a guidewire (1) which goes through the guide device to assist in more precise targeting of the blade and entry into the spinal area. See also (Col. 11, lines 20-40). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Jacobson having at least a guidewire extending through the blade and nested dilators in view of Ogawa et al. to have improved access to the spinal area and improved precision during surgery.”

Applicants respectfully submit that the Examiner mischaracterizes the reference. The cited portion of the Ogawa et al. reference (Col. 11, lines 20-40) does not teach a “guide device to assist in more precise targeting of the *blade*.” (emphasis added). This excerpt does not describe a blade, but merely dilator 2 tubes 7 fitted onto the guidewire 1. (see Col. 11, lines 34-35: “The tube 7a having the smallest diameter is fitted on the guidewire 1.”) Guidewire 1 appears to be removed after the dilator tubes are placed, and, therefore, does not aid in more precise targeting of any blade: “Subsequently, the first tube 7a is fitted on the inserted guidewire 1, and the distal end of the first tube 7a is inserted to the region P of surgical object of the tissue along the guidewire 1. Thereafter, the guidewire 1 is removed.” (Col. 13, lines 29-32).

The Supreme Court in *KSR Int'l Co. v. Teleflex Inc.* quotes *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006):

“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”.

Emphasis added; see page 14 of the April 30, 2007 decision. The Court further stated:

a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.

See page 14 of the April 30, 2007 decision. The Examiner has not provided reasoning with rational underpinning to support the conclusion of obviousness. The Examiner asserts that it would have been obvious “to construct the device of Jacobson having at least a guidewire extending through the blade and nested dilators in view of Ogawa et al. to have improved access to the spinal area and improved precision during surgery.” Additionally, in the Advisory Action, the Examiner asserts that it is known in the art to use wires or a wiring aid to keep tools, access portals, or cutting devices, etc. in line with a surgical site to assist with the surgery performed externally.” Applicants submit that Jacobson already teach using the cannula for positioning and guiding the rongeur forceps to the surgical site, thus there is no motivation for one of ordinary skill in the art to modify Jacobson to add another wire inside the cannula to somehow keep the rongeur forceps in line with the surgical site. Such a modification would appear to be redundant in view Jacobson’s teaching of using a cannula to guide the forceps. MPEP 2143.01 III states:

The mere fact that references can be combined or modified does not render the resultant combination obvious unless ****>**the results would have been predictable to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007)

The Examiner appears to be relying on the fact that Jacobson and Ogawa et al. could be combined in some fashion, without providing the necessary rational reasoning for an obviousness rejection. Additionally, it would appear that even if one were to add a wire as taught by Ogawa to guide or keep the forceps of Jacobson in line with the surgical site, the result would be to insert a wire into the disc space because that is the desired location of the forceps of Jacobson. Applicants submit that such a combination would not result in the instrument as claimed. Thus, even if one were to combine the teachings of Jacobson and Ogawa, one would not achieve the device as claimed. The rejection is thus in error.

Jacobson does not appear to teach each and every element of independent claim 2 and Ogawa et al. do not appear to cure the failings of Jacobson for reasons similar to those stated above regarding claim 1. As stated by the Examiner on page 2 of the Office Action, Jacobson does not teach “a layered, nested incremental portal assembly in the device and also wherein the placement wire is relocated to be within part of the blade.” The Examiner states on pages 2 to 3 of the Office Action that “Ogawa et al. discloses device to assist in accessing a surgical site having nested, tube-like guides (Fig. 1A, and 8a-d)” Even assuming, for the sake of argument, that the tubes 7a-7d constitute “the plurality of nested members,” they do not include a dissector member that is slidably positionable over the first and second wires (with both wires being received within at least a portion of the dissector member) and is configured to provide an access opening. Also, they do not include a sleeve member that is slidably positionable over the dissector member. MPEP 2143.03 states:

"All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Neither Jacobson nor Ogawa et al. appear to show the elements contained in claim 2. Additionally, the Examiner has not provided rational reasoning as to why one of ordinary skill in the art would have been motivated to modify Jacobson and/or Ogawa et al. to achieve the claimed structure. The rejection is thus in error.

For similar reasons as discussed above regarding independent claim 1, Jacobson fails to teach “a blade member slidably positioned over the first wire with the first wire received within at least a portion of the blade member”, as recited in claim 16. There is no motivation for one of ordinary skill in the art to modify Jacobson to add a wire to guide or place the forceps because Jacobson specifically teach placing a cannula at the surgical site and inserting the forceps through the cannula as a guiding means. The Examiner asserts, on page 3 of the Office Action, that the motivation for combining Jacobson and Ogawa is “to have improved access to the spinal area and improved precision during surgery.” Applicants submit that there is no support for such an assertion. As discussed above, Jacobson already teach placing a cannula at the surgical site and inserting the forceps through the cannula to reach the surgical site. Applicants submit that as Jacobson already teach a means that appears to

provide access and precision for surgery, there is no motivation for one of ordinary skill in the art to add a guidewire.

Further, Applicants submit that adding a guidewire somehow inserted through the forceps would not achieve the Examiner's asserted advantages. Jacobson teach using the cannula and forceps for removing disc material. (Col. 2, lines 40-46). Applicants submit that inserting a wire into the disc and passing the forceps of Jacobson over the wire would not appear to provide the movement and access necessary for the Jacobson device to function in removing the disc material. Thus, combining Jacobson and Ogawa would appear to render the Jacobson device unsuitable for its intended purpose. Jacobson thus appears to teach away from any combination with Ogawa. Applicants submit the rejection is in error.

Claims 14-15 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Jacobson (U.S. Patent No. 4,545,374) and Ogawa et al.(U.S. Patent No. 5,976,146) and further in view of Koros et al. (U.S. Patent No. 5,928,139). For at least the reasons set forth above, independent claim 2, from which claims 14-15 depend, is believed patentable over Jacobson in view of Ogawa et al. Koros et al. do not appear to cure the failings of Jacobson in view of Ogawa et al. Thus any combination of Jacobson, Ogawa et al. and Koros et al. also fails to teach or suggest the elements of claims 14-15. This rejection is thus in error.

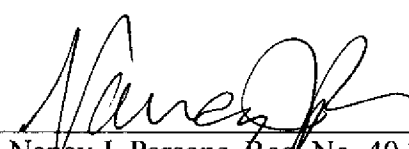
It is respectfully submitted that the claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Erik E. EMSTAD et al.

By their attorney,

Date: 11/7/08


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